

**Food and Drug Administration**  
**FY 2012 Congressional Budget Request**  
Table of Contents

	<b><u>Page</u></b>
<b><u>Narrative by Activity:</u></b>	
FDA Program Resources Table	<b>456</b>
Program Description and Accomplishments	<b>457</b>
Five Year Funding History	<b>463</b>
Budget Request	<b>463</b>

## INFRASTRUCTURE GSA RENT, OTHER RENT AND WHITE OAK CONSOLIDATION

The following table displays funding levels for FY 2010 through FY 2012.

**FDA Program Resources Table  
(Dollars in Thousands)**

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
<b>Program Level</b>	<b>\$301,424</b>	<b>\$301,913</b>	<b>\$306,434</b>	<b>\$406,611</b>	<b>\$105,187</b>
GSA Rent	\$175,840	\$177,709	\$173,417	\$214,302	\$38,462
Other Rent	\$84,088	\$85,668	\$91,066	\$123,788	\$39,700
White Oak	\$41,496	\$38,536	\$41,951	\$68,521	\$27,025
<b>Budget Authority</b>	<b>\$248,656</b>	<b>\$248,658</b>	<b>\$248,656</b>	<b>\$318,176</b>	<b>\$69,520</b>
GSA Rent	\$145,260	\$145,261	\$145,260	\$167,826	\$22,566
Other Rent	\$64,860	\$64,861	\$64,860	\$86,212	\$21,352
White Oak	\$38,536	\$38,536	\$38,536	\$64,138	\$25,602
<b>User Fees</b>	<b>\$52,768</b>	<b>\$53,255</b>	<b>\$57,778</b>	<b>\$88,435</b>	<b>\$35,667</b>
<b>GSA Rent</b>	<b>\$30,580</b>	<b>\$32,448</b>	<b>\$28,157</b>	<b>\$46,476</b>	<b>\$15,896</b>
PDUFA	\$22,328	\$25,632	\$19,905	\$25,544	\$3,216
MDUFMA	\$4,264	\$2,361	\$4,264	\$5,019	\$755
ADUFA	\$885	\$659	\$885	\$1,115	\$230
AGDUFA	\$305	\$105	\$305	\$340	\$35
Tobacco	\$2,798	\$3,691	\$2,798	\$5,503	\$2,705
Voluntary Qualified Importer Program (VQIP) User Fee				\$3,920	\$3,920
Food Reinspection				\$1,338	\$1,338
Generic Drugs				\$1,943	\$1,943
Medical Product Reinspection				\$1,026	\$1,026
Recall User fee				\$434	\$434
International Courier User Fee				\$294	\$294
<b>Other Rent</b>	<b>\$19,228</b>	<b>\$20,807</b>	<b>\$26,206</b>	<b>\$37,576</b>	<b>\$18,348</b>
PDUFA	\$16,275	\$18,991	\$23,253	\$29,841	\$13,566
MDUFMA	\$1,376	\$1,087	\$1,376	\$1,620	\$244
ADUFA	\$162	\$121	\$162	\$204	\$42
AGDUFA	\$72	\$105	\$72	\$80	\$8
Tobacco	\$1,343	\$503	\$1,343	\$1,550	\$207
Voluntary Qualified Importer Program (VQIP) User Fee				\$2,240	\$2,240
Food Reinspection				\$592	\$592
Generic Drugs				\$578	\$578
Medical Product Reinspection				\$455	\$455
Recall User fee				\$248	\$248
International Courier User Fee				\$168	\$168
<b>White Oak</b>	<b>\$2,960</b>	<b>\$0</b>	<b>\$3,415</b>	<b>\$4,383</b>	<b>\$1,423</b>
PDUFA	\$2,960	\$0	\$3,415	\$4,383	\$1,423

The FDA Infrastructure Program operates under the following legal authorities and executive orders.

The following are legal authorities for GSA Rent and Other Rent and Rent Related activities:

- The Public Buildings Act of 1959 (40 USC 601-619)

- Public Buildings Act: Public Buildings Amendments of 1972 (P.L. 92-313, 86 Stat. 216)
- Public Buildings Cooperative Use Act of 1976 (P.L. 94-541, 90 Stat 2505)
- Public Buildings Amendments of 1988 (P.L.100-678, 102 Stat 4049)
- The Federal Property and Administrative Services Act of 1949 (40 USC 486[d] and [e])
- Omnibus Appropriations Act of 2009 (P.L. 111-8, 123 Stat. 524)
- Energy Independence & Security Act of 2007 (P.L. 10-140, 121 Stat. 1492)

The following authorities establish the consolidation of FDA Headquarters facilities at the White Oak Campus:

- The Food and Drug Administration Revitalization Act (21 U.S.C. 379b)
- Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399)
- Treasury, Postal Service and General Government Appropriations Act (5 U.S.C.)

Allocation Method: Direct Federal/Intramural

## **Program Description and Accomplishments**

The Infrastructure Program supports FDA's mission of protecting the nation's public health by providing the Centers and ORA with secure and cost-effective office and laboratory space in which to perform mission critical work. The Infrastructure Program includes three areas:

- GSA Rental Payments
- Other Rent and Rent-Related Activities
- The FDA White Oak Consolidation.

### **GSA Rental Payments**

Base Amount: \$175,840,000 (BA: \$145,260,000 / UF: \$30,580,000)

The GSA Rental account includes FDA rental payments to the General Services Administration (GSA) covering FDA's office and laboratory facilities and to the Department of Homeland Security (DHS) for standard level security services at these facilities.

FDA currently occupies over 5.6 million square feet of GSA-owned or -leased office, laboratory, and warehouse space. More than two-thirds of the GSA and DHS rent charges for GSA-owned or GSA-leased space are for facilities in the Washington, D.C. area. The largest amounts include charges for CFSAN's College Park complex and the newly occupied buildings at the White Oak, Maryland campus, now housing most of OC, CDER, and CDRH. In total, FDA-occupied GSA space comprises approximately 282 buildings including District Offices, Regional Offices, laboratories, and resident posts across the nation and in Puerto Rico.

The GSA Rent program continues to conduct numerous activities to ensure that the FDA workforce has the space and security necessary to carry out FDA's mission of protecting the public health in an efficient and effective manner.

In FY 2010, with the OC and ORA migration to the FDA White Oak campus, FDA vacated space in five Headquarters locations but immediately backfilled four of these locations with newly hired OC staff and with staff vacating the Parklawn Building. In total, FDA reduced its space in the Parklawn Building by 279,000 rentable square feet (RSF). The remaining 124,000 RSF occupied by FDA will be vacated by January 31, 2011. In addition to two new buildings on the White Oak campus, FDA acquired expansion space for CFSAN at University Station in College Park. FDA's Office of Criminal Investigations (OCI) opened two new field offices and expanded one field office. ORA opened two new Resident Posts, acquired expansion space for four Resident Posts and one Border Station, relocated 11 Resident Posts and two Border Stations, and closed one Resident Post. ORA also acquired expansion space for one District Office.

FDA is working with DHHS to promote maximum utilization of Federal workspace, consistent with mission requirements, and to maximize its value to the Government. FDA strives to be cost effective, energy efficient and to acquire the necessary space to meet the mission and nationally recognized standards.

#### **Other Rent and Rent-Related Activities**

Base Amount: \$84,088,000 (BA: \$64,860,000 / UF: 19,228,000)

The Other Rent and Rent-Related Activities account includes commercial rent and rent-related charges that are not part of the GSA Rent account. These funds cover costs for operating and maintaining FDA and GSA facilities located nationwide. Costs include commercial rent, operation and maintenance contracts, janitorial and grounds maintenance contracts, and above standard security and guard services contract costs. The program also funds standard utilities in FDA owned facilities, essential overtime utilities in laboratories and data centers, and other above-standard level services not provided by GSA in GSA-managed facilities. These accounts directly support the FDA workforce in meeting its public health mission by providing safe, efficient and secure facilities.

FDA is working on the implementation of numerous energy savings efforts that will decrease long term utility usage and costs, increase the life span and efficiency of operating and maintaining facilities, and save on overall energy usage. These changes will help FDA realize a significant savings in Other Rent and Rent Related. The implementation of these types of projects supports and meets the requirements set forth in Executive Order 13423 Strengthening Federal Environmental, Energy, and Transportation Management. These projects contribute to meeting the requirements of the Department of Health and Human Services (DHHS) Efficient Energy Management Assessments, the Energy Policy Act of 2005, and the DHHS Sustainable and High Performance Buildings Policy, High Performance Buildings Implementation Plan and the

2006 Federal Leadership in High Performance and Sustainable Buildings Memorandum of Understanding.

FDA continues to issue Utility Energy Service Contracts (UESC) for FDA owned facilities. These contracts are based on the implementation of specific energy and water conservation measures (ECMs) including:

- replacing chillers and cooling towers
- converting laboratory air handling units to new variable air volume controls
- upgrading and enhancing laboratory electrical systems.

These ECMs are estimated to save almost \$2.0 million annually in water, sewer, electricity and fuel costs, representing a 35 percent utility cost savings. In addition, FDA installed advanced meters during FY 2010 which were linked to the Building Automation System which generates monthly reports documenting the energy savings. FDA will use this information to identify areas using excess energy and upgrade to more efficient, cost effective items.

Washington Gas and FDA conducted a second preliminary audit in March 2010 to investigate and survey ten more potential ECM's such as:

- a boiler stack economizer
- chiller replacement
- boiler blow-down/heat recovery
- water conservation measurements
- lighting upgrades.

These measures will provide approximately \$400,000 of projected annual energy savings costs. This proposed UESC also includes one facility improvement measure (FIM), which consists of electrical upgrades\replacement of the aged switchgear system. The replacement of this equipment provides the facility reliable power and improves the facility condition index of the asset. FDA is reviewing the preliminary audit and will determine whether to proceed with an investment grade audit that will provide more detailed analyses of the cost savings and a more accurate construction cost.

FDA is also considering an energy saving contract for the ORA District Laboratory and Office in Irvine, CA with the Southern California Edison Electric (SCE) Power Company. If determined to be cost effective and economically feasible, FDA will proceed with awarding the contract. SCE surveyed the facility and determined that there were several opportunities to be pursued, including but not limited to:

- on- and off-site renewables
- roof mounted solar panels
- a solar screen wall
- lighting controls such as dimmers and sensors
- high efficiency motors
- advanced meters
- replacement of first generation T8 lighting
- upgrades to the HVAC-DDC controls.

Actual project cost and cost savings are not known at this time but appear to have great potential as viable energy conservation measures. FDA anticipates the submission of a formal-preliminary audit before the end of the fiscal year.

Awarding additional UESCs and procuring renewable energy will contribute to HHS sustainability goals established in the HHS Strategic Sustainability Plan developed in accordance with Executive Order 13514, "Federal Leadership in Environmental, Energy and Economic Performance." More specifically, FDA's planned FY 2012 activities related to UESCs and renewable energy will help reduce Scope 1 and 3 greenhouse gas emissions.

### **White Oak Consolidation**

Base Amount: \$41,496,000 (BA: \$38,536,000 / UF: \$2,960,000)

FDA's headquarters' consolidation to the White Oak complex is replacing and centralizing existing geographically disparate facilities with new, state-of-the-art laboratories, office buildings and support facilities into one location. While the GSA appropriation funds the design and construction of the new buildings at White Oak, FDA's appropriation and PDUFA user fees fund building fit-out and move costs. FDA initiated relocation activities to White Oak in FY 2002.

During FY 2010 approximately 1,026 employees moved to the White Oak Campus. The total number of employees currently working on the White Oak Campus is 5,496. A Child Care Center will be completed in 2011. If adequate GSA construction funds are appropriated in FY 2012 and 2013, during FY 2014 and 2015, FDA plans to relocate another 3,393 employees to the White Oak Campus, for a total on Campus of 8,889, and the current phase of the consolidation will conclude in FY 2015.

Completed design plans include:

- The Southeast Parking Garage — plans completed in May 2009 — will be built pending appropriation of GSA construction funding and completed by FY 2014.
- Buildings 52 and 72 — the Life Sciences-Biodefense Laboratories II and III and the vivarium — plans are complete; construction began fourth quarter FY 2010.
- Buildings 71 and 75 — construction is scheduled to begin in mid-FY 2011.

Buildings 25, 45 (Distribution Facility) and the Communications Facility are scheduled to be designed in FY 2011.

Based on FY 2010 funding and the FY 2009 Master Plan, GSA considers the 130-acre White Oak Campus project to be 70 percent complete. FDA is working with the GSA to secure GSA construction funding for the remaining facilities included in the current White Oak Campus Master Plan design.

However, FDA is experiencing an unprecedented and dramatic surge in staffing and facility needs that will cause FDA facility requirements to exceed the scope of the 2009 Master Plan. This staffing surge is based on FY 2008 and FY 2009 appropriation increases, budgeted increases for FY 2010, and growth associated with the Center for

Tobacco Products. On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act, giving FDA the authority to regulate the manufacturing, marketing and sale of tobacco products. Implementing this legislation will require FDA to hire as many as 700 additional professionals to support the new Center for Tobacco Products.

FDA is working with GSA to secure funding for environmental planning, design, and construction for facilities to support our growth. Where necessary, FDA will acquire temporary leased office space to accommodate program growth until the facilities are available.

FDA White Oak funding will be used for:

- furniture
- information technology and telecommunications equipment and infrastructure
- AV Equipment
- security equipment and cabling for Office Building 75.

White Oak will also fund security equipment and communications networks for Office Building 25 and the Auxiliary Support Facilities, such as Visitor Center Screening and Communications Facility. Security screening equipment for the Southeast Garage will also be installed.

In addition, funding for operations and logistics functions on the White Oak Campus is required. There are currently 5,496 employees on Campus and as construction and consolidation grow, that number is increasing exponentially. Therefore, services are needed to operate:

- a Campus transportation program including parking management and a Campus Shuttle and Circulator Bus program
- a 1,600-seat Conference Center
- labor and loading dock services
- laboratory maintenance program
- other central services.

As the Campus continues to grow, continued funding will be needed to coordinate and implement activities associated with operations and logistics.

Funding for Campus operations and logistics is critically needed as the Campus has tripled in size over the last five years; and, in the 2013 to 2015 timeframe, the Campus will grow by another 60 percent. To keep pace with this growth and, as a result of its success in service delivery, the central Campus operations budget will continue to grow. As this program continues to expand and FDA capitalizes on opportunities to gain efficiencies, these funds must be included within the FDA budget as a recurring and increasing need.

## Promoting Efficiency

FDA's consolidation at White Oak is not only critical to strengthening public health and national security through scientific integration, but also provides an environment that encourages efficiency, creativity and superior performance, while strategically using our human capital. The Campus is being built with centrally shared functional spaces such as document rooms and conference areas to make the most effective use of resources and eliminate redundant activities across FDA Centers. By providing well-organized services on a central basis, consistent with the design of the facility, FDA gains economies of scale and saves on costs.

### FIVE YEAR FUNDING TABLE – GSA RENT

The following table displays funding levels from FY 2007 through FY 2011.

<b>Fiscal Year</b>	<b>Program Level</b>	<b>Budget Authority</b>	<b>User Fees</b>
FY 2007 Actual	\$138,896,000	\$126,871,000	\$12,025,000
FY 2008 Actual	\$145,111,000	\$130,611,000	\$14,500,000
FY 2009 Actual	\$156,399,000	\$133,590,000	\$22,809,000
FY 2010 Actual	\$177,709,000	\$145,261,000	\$32,448,000
FY 2011 Continuing Resolution	\$173,417,000	\$145,260,000	\$28,157,000

### FIVE YEAR FUNDING TABLE – OTHER RENT AND RENT-RELATED ACTIVITIES

The following table displays funding levels from FY 2007 through FY 2011.

<b>Fiscal Year</b>	<b>Program Level</b>	<b>Budget Authority</b>	<b>User Fees</b>
FY 2007 Actual	\$49,906,000	\$42,000,000	\$7,906,000
FY 2008 Actual	\$64,646,000	\$50,278,000	\$14,368,000
FY 2009 Actual	\$77,866,000	\$62,533,000	\$15,333,000
FY 2010 Actual	\$85,668,000	\$64,861,000	\$20,807,000
FY 2011 Continuing Resolution	\$91,066,000	\$64,860,000	\$26,206,000

## FIVE YEAR FUNDING TABLE – WHITE OAK

The following table displays funding levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2007 Actual	\$35,657,000	\$25,552,000	\$10,105,000
FY 2008 Actual	\$42,726,000	\$38,536,000	\$4,190,000
FY 2009 Actual	\$41,439,000	\$38,779,000	\$2,660,000
FY 2010 Actual	\$38,536,000	\$38,536,000	\$0
FY 2011 Continuing Resolution	\$41,951,000	\$38,536,000	\$3,415,000

### Budget Request

The FY 2012 budget request for the Infrastructure program is \$406,611,000. The request includes \$318,176,000 in Budget Authority and \$88,435,000 in User Fees. This amount is an increase of \$69,520,000 in Budget Authority and \$35,667,000 in User Fees for a total of \$105,187,000 above the FY 2010 Enacted Level.

The base funding for FDA's Infrastructure Program is \$301,424,000 including \$248,656,000 in Budget Authority and \$52,768,000 in User Fees.

### **GSA Rental Payments** (Base: \$175,840,000)

FDA requests \$214,302,000 for GSA Rental Payments which is an increase of \$38,462,000 over the base. The increase includes \$22,566,000 in Budget Authority and \$15,896,000 in User Fees. The total request includes \$167,826,000 in Budget Authority and \$46,476,000 in User Fees.

The rental properties that provide office and laboratory space for FDA's 12,000 employees are essential facilities that allow FDA to perform its vital public health mission. Base funding for GSA Rental Payments covers the cost of rental payments to GSA for FDA's five million square feet of GSA rented office and laboratory space, as well as payments to the Department of Homeland Security for guard services and security systems at these facilities.

**Other Rent and Rent-Related** (Base: \$84,088,000)

FDA requests \$123,788,000 for Other Rent and Rent Related which is an increase of \$39,700,000 over the base. The increase includes \$21,352,000 in Budget Authority and \$18,348,000 in User Fees. The total request includes \$86,212,000 in Budget Authority and \$37,576,000 in User Fees.

It is important that FDA keep its infrastructure up-to-date and efficient to support our staff while executing our regulatory mission. This budget request allows FDA to operate, maintain and secure its facilities in an appropriate and sustainable manner. This budget request will cover the escalating costs in commercial rent, security, service contracts, and utilities without reducing essential FDA programs.

**White Oak Consolidation** (Base: \$41,496,000)

FDA requests \$68,521,000 for the White Oak Consolidation which is an increase of \$27,025,000 over the base. The increase includes \$25,602,000 in Budget Authority and \$1,423,000 in User Fees. The total request includes \$64,138,000 in Budget Authority and \$4,383,000 in User Fees.

The remaining construction on the White Oak Campus includes the two largest laboratories – the Life Sciences-Bioterrorism Laboratories II and III – and facilities to support the White Oak laboratories. These laboratories and related campus improvements include nearly 1.2 million square feet of specialized scientific and support facilities.

In August 2010 GSA awarded a contract for construction of the Life Sciences-Biodefense laboratories and other remaining White Oak facilities. This budget request allows FDA to pay their share of the costs to make the laboratory operational. FDA will invest in security, communications network, outfitting, commissioning and providing the essential equipment and infrastructure for the Life Sciences-Biodefense Laboratories II and III, as well as supporting facilities in the Southeast Quadrant to ensure that they are safe, certified and operational.